

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCTS LIABILITY) MDL No. 02419
LITIGATION) Docket No. 1:13-md-2419-RWZ

This document relates to:)

All of the cases against the Box Hill Defendants)

_____)

**THE BOX HILL DEFENDANTS' FIRST INTERROGATORIES, REQUESTS FOR
PRODUCTION OF DOCUMENTS AND REQUESTS FOR ADMISSION PROPOUNDED
TO CARLA CONIGLIARO**

Come the Defendants Box Hill Surgery Center, L.L.C., Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., L.L.C. (collectively "Box Hill Defendants"), pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories, Requests for Production of Documents and Requests for Admission to Carla Conigliaro.

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within thirty (30) days after the service date of these Interrogatories.

You are under a duty to seasonably supplement your response with respect to any Interrogatory directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

DEFINITIONS

1. As used in this document, the term "person(s)" and "individual(s)" mean any natural individual in any capacity whatsoever or any entity or organization, including divisions, departments, and other units therein, and shall include, but not be limited to, a public or private corporation, partnership, joint venture, voluntary or unincorporated association, organization, proprietorship, trust, estate, governmental agency, commission, bureau, or department.

2. As used in this document, the term "document" means any medium upon which intelligence or information can be recorded or retrieved, and includes without limitation, the original and each copy, regardless of origin and location, of any book, pamphlet, periodical, letter, memorandum (including any memorandum or report of a meeting or conversation), invoice, bill, order form, receipt, financial statement, accounting entry, diary, calendar, telex, telegram, cable, report, record, contract, agreement, study, handwritten note, draft, working paper, chart, paper, print, laboratory record, drawing or sketch, graph, index, lists, tape, photograph, microfilm, data processing card, or any other written recorded, transcribed, punched, taped, filmed, or graphic matter, however produced or reproduced, which is in your possession, custody or control, or which was, but is no longer, in your possession, custody, or control.
3. As used in this document, the terms "identification," "identify," or "identity," when used in reference to a natural individual, require you to state his or her full name and residential and business address. Use of the term "document" in connection with the Interrogatories requires you to state the number of pages and the nature of the documents, its title, its date, the name or names of its authors, and recipients and its present location and custodian.
4. "You" and "your" refers to Carla Conigliaro and each of its present and former agents, representatives and employees, attorneys and accountants, and each person acting or purporting to act on its behalf.
5. "Communication" means any oral or written utterance, notification, or statement of any nature whatsoever, by and to whomsoever made, including, but not limited to, correspondence, conversation, dialogue, discussions, interviews, consultants, and any other understanding between or among two or more persons.

INSTRUCTIONS

1. With respect to each Interrogatory, in addition to answering the question, you are to identify all documents that support, refer to, or evidence the subject matter of each Interrogatory and your answer thereto.

If any or all identified documents are no longer in your possession, custody, or control because of destruction, loss or any other reason, then you must do the following with respect to each and every document:

- A. Describe the nature of the document;
- B. State the date of the document;
- C. Identify the persons who sent and received the original and the copy of the document;
- D. State in as much detail as possible the contents of the documents; and

E. State the manner and date of disposition of the document.

If you contend that you are entitled to withhold from production any or all documents identified herein on the basis of attorney-client privilege, the work-product doctrine, or any other ground, then do the following with respect to each and every document.

- A. Describe the nature of the document;
 - B. State the date of the document;
 - C. Identify the persons who sent and received the original and a copy of the document;
 - D. State the subject matter of the document; and,
 - E. State the basis upon which you contend you are entitled to withhold the document from production.
2. All documents produced should be organized and labeled to correspond to the specific Request in response to which they are being made available or should be produced as they are kept in the usual course of business.
 3. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests and information that might otherwise be construed as outside their scope.
 4. The term "any" should be construed to include the word "all," and "all" should be construed to include "and."
 5. The present tense should be construed to include the past tense, and the past tense should be construed to include the present tense.
 6. The singular should be construed to include the plural, and the plural should be construed to include the singular.
 7. The terms "he" and "his" should be construed to include the words "she" and "her" or "hers," respectively and vice versa.
 8. "Relating to," when referring to a document shall mean mentioning, describing, connected to or with, or discussing the stated subject matter.

INTERROGATORIES

On March 19, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Carla Conigliaro*. In order to minimize the impact of discovery on Carla Conigliaro, these Box Hill Defendants **hereby adopt and incorporate, as if stated fully herein, Interrogatories 1-6** from the Saint Thomas Entities' *First Set of Interrogatories*. The "new" Interrogatories begin at Number 7.

1-6. [The Box Hill Defendants adopt and incorporate, as if stated fully herein, Interrogatories 1-6 from the *Saint Thomas Entities' First Set of Interrogatories*.]

ANSWER:

7. Describe in detail your role at NECC and Ameridose, including job title, job description, and a description of your daily duties and activities in 2011 and 2012.

ANSWER:

8. Describe in detail the steps NECC took to compound, process, stopper, seal, package, and ship methylprednisolone acetate ("MPA") in 2011 and 2012, including but not limited to:

- a) The names of the individuals performing each step;
- b) The job titles for the individuals performing each step;
- c) The specific cleanroom or location in NECC's facility where each step took place;
- d) The tools, equipment or machinery used for each step;
- e) Any changes to NECC's methods and procedures for compounding MPA, or the location where compounding MPA took place, that occurred in 2011 or 2012.

ANSWER:

9. Identify the total amount of MPA that NECC, and separately Ameridose, produced in each quarter of 2010, 2011 and 2012.

ANSWER:

10. Identify the types of vials and closures NECC sued for MPA lots numbered 052122012@68m 06292012@26 and 08102012@51 (collectively “Contaminated Lots”), including whether the vials and enclosures were prewashed or presterilized and identify their manufacturer(s).

ANSWER:

11. Identify any and all complaints that NECC and Ameridose received related to the sterility or safety of their products, including but not limited to, complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

12. Identify any customers of NECC and Ameridose who performed site visits prior to placing orders with either company.

ANSWER:

13. Describe any policies, procedures or protocols relating to or regarding customer site visits to the NECC facility, including the areas you allowed customers to inspect.

ANSWER:

14. Identify any customers who asked for information about prior recalls of NECC and Ameridose products prior to placing orders with either company.

ANSWER:

15. Identify and describe any information you gave customers about recalled NECC and Ameridose products in 2011 and 2012.

ANSWER:

16. Identify any and all complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to, complaints by customers, current and former employees and state and federal government agencies.

ANSWER:

17. Identify and describe any way in which NECC's cleanrooms were modified, altered, or expanded by NECC or Ameridose.

ANSWER:

18. Identify any policies, procedures, or guidelines in place at NECC in 2012 that encouraged employees to disclose mistakes in the compounding process, even if the mistakes necessitated destruction of product or halting production.

ANSWER:

19. Describe all disciplinary or enforcement action taken against NECC or Ameridose by any state or federal government agency.

ANSWER:

20. Describe in detail Lisa Conigliaro Cadden's role at NECC in 2011 and 2012.

ANSWER:

REQUESTS FOR PRODUCTION

On March 19, 2015, the Saint Thomas Entities sent their First Set of Interrogatories, Requests for Production and Requests for Admission to Carla Conigliano. In order to minimize the impact of discovery on Carla Conigliano, these Box Hill Defendants **hereby adopt and incorporate, as if stated fully herein, Requests for Production 1-39 from the Saint Thomas Entities' First Requests for Production.** The "new" Requests for Production begin at Number 40.

1-39. [The Box Hill Defendants adopt and incorporate, as if stated fully herein, Requests for Production 1-39 from the Saint Thomas Entities' First Requests for Production.]

RESPONSE:

40. Produce all correspondence between you and any of the Box Hill Defendants, their employees, agents or representatives.

RESPONSE:

41. Produce all correspondence and documents referring or relating to any of the Box Hill Defendants' purchase of MPA from NECC in 2012.

RESPONSE:

42. Produce all documents, produced by the government to you during any civil criminal, or administrative proceedings related to NECC's contaminated MPA.

RESPONSE:

43. Produce all policies, procedures, guidelines, instructions and training documents referring or relating to the compounding of MPA at the NECC facility.

RESPONSE:

44. Produce all documents referring or relating to NECC or Ameridose sending samples of insufficient size or volume to comply with USP 71 to ARL or any other testing laboratory.

RESPONSE:

45. Produce all documents referring or relating to any sterility potency, endotoxin, or fungal testing that you received from ARL or any other laboratory related to MPA compounded by NECC or Ameridose in 2011 and 2012.

RESPONSE:

46. Produce all correspondence and documents referring or relating to fungal blooms growth in or near NECC's cleanrooms.

RESPONSE:

47. Produce documents referring or relating to complaints or communications with Liberty regarding the design, manufacture or installation of the clean rooms at the NECC facility.

RESPONSE:

48. Produce all documents referring or relating to any complaints that NECC or Ameridose received related to the sterility or safety of their products, including but not limited to, complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

49. Produce all documents referring or relating to any complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

50. Produce all correspondence and documents referring or relating to NECC's response to the meningitis outbreak, including but not limited to, steps NECC took to prepare for any inspections of its facility.

RESPONSE:

51. Produce all training and instructional material for sales staff at NECC or MSM.

RESPONSE:

REQUESTS FOR ADMISSION

On March 19, 2015, the Saint Thomas Entities sent their *First Set of Interrogatories, Requests for Production, and Requests for Admission to Carla Conigliaro*. In order to minimize the impact of discovery on Carla Conigliaro, these Box Hill Defendants **hereby adopt and incorporate, as if stated fully herein, Requests for Admission 1-12** from the *Saint Thomas Entities' First Requests for Admission*. The new requests begin at Number 13.

1-12. [The Box Hill Defendants adopt and incorporate, as if stated fully herein, Requests for Admission 1-12 from the *Saint Thomas Entities' First Request for Admission*.]

RESPONSE:

13. Admit that, had any of the Box Hill Defendants asked for a copy of NECC's license prior to and including 2012, you would have provided a valid and up-to-date Tennessee pharmacy license, and a license with the Maryland Board of Pharmacy.

RESPONSE:

14. Admit that NECC represented to its customers, including the Box Hill Defendants, that it met or exceeded USP 797 standards.

RESPONSE:

15. Admit that NECC represented to the Box Hill Defendants that its products, including MPA, were safe and sterile.

RESPONSE:

16. Admit that the Massachusetts Board of Pharmacy ("Mass BoP") inspected NECC on or about May 24, 2011.

RESPONSE:

17. Admit that as a result of its inspection on or about May 24, 2011 the Mass BoP issued an inspection report documenting its findings.

RESPONSE:

18. Admit that NECC failed to submit a copy of the Mass. BoP's May 24, 2011 inspection report to the Maryland Board of Pharmacy.

RESPONSE:

19. Admit that you owed a duty to NECC's customers to ensure that its MPA was sterile prior to distributing it.

RESPONSE:

Respectfully submitted,

/s/ Gregory K. Kirby

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CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing Interrogatories, Requests for Production of Documents, and Requests for Admission has been served on the below listed counsel for Carla Conigliaro on July 30, 2015 via U.S. Mail, postage pre-paid. Thereafter, a copy was filed on the Court's CM/ECF system to ensure that all interested parties can access it.

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/s/ Gregory K. Kirby

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